864.9285 Automated cell-washing centrifuge for immuno-hematology.
864.9300 Automated Coombs test systems.
864.9320 Copper sulfate solution for specific gravity determinations.
864.9400 Stabilized enzyme solution.
864.9550 Lectins and protectins.
864.9575 Environmental chamber for storage of platelet concentrate.
864.9600 Potentiating media for in vitro diagnostic use.
864.9650 Quality control kit for blood banking reagents.
864.9700 Blood storage refrigerator and blood storage freezer.
864.9750 Heat-sealing device.
864.9875 Transfer set.

Subpart K—Products Used In Establishments That Manufacture Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

864.9900 Cord blood processing system and storage container.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

EDITORIAL NOTE: Nomenclature changes to part 864 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html*.

[52 FR 17732, May 11, 1987, as amended at 69 FR 12273, Mar. 16, 2004]

§ 864.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device